UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: TRACK TWO SETTLEMENT	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' SUPPLEMENTAL SUBMISSION IN SUPPORT OF A REBALANCED TRACK TWO SETTLEMENT

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I. INTRODUCTION

At the Track Two settlement fairness hearing held July 7, 2011, the Court requested that Plaintiffs make a supplemental filing explaining in much greater detail the nature of the drugs at issue in Track Two, the discovery undertaken into those drugs, and an identification of which drugs were the subject of the Court's April 10, 2006 order striking so-called "new drugs." The Court requested an evidentiary declaration from Plaintiffs' expert, Dr. Raymond Hartman. The Court also asked Plaintiffs to re-examine the redistribution proposal in accord with the Court's observations at the July 7 hearing, and the Court encouraged the parties to continue mediation efforts with objectors.

This supplemental submission responds to the Court's questions. It also proposes a "rebalancing" of the consumer-TPP allocation, ***under which TPP Allocation Counsel have agreed to provide an additional $3,125,000 to consumers***. This results in a gross consumer-TPP split of 20%/80% (instead of 17.5%/22.5%, as originally proposed), or $20 million to consumers and $100 million to TPPs.[1]

In sum, the modified reallocation and redistribution plan accomplishes the following, including the changes that we recommended in Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation (Dkt. No. 7647):

1. Class 1 and 3 consumers receive ***double*** their actual damages incurred on eligible administrations of Group A drugs, ***even for administrations outside of the Court's "Heartland Period."***

2. Class 1 and Class 3 consumers administered Epogen receive a flat payment of $5 and $50, respectively, for all administrations of Group A drug Epogen, for which they incurred either minimal or no damage but for which they are providing a release.

[1] Although consumers and TPPs share notice and administration costs, TPPs bear a disproportionate amount of those costs given that (i) the costs are deducted before the consumer/TPP allocation is made and (ii) consumer notice costs were much higher than TPP notice costs.

3. Class 3 consumers electing the "Easy Pay" refund option receive a ***full*** $35 flat payment, instead of $2.04 under the original pro-ration.

This submission also proposes additional redistribution measures that result in a ***240% increase*** in the recovery for Group B drugs, without reducing the recovery proposed for the Group A drugs in Plaintiffs' prior proposal submitted on July 5, 2011 (with the exception of Epogen).

Plaintiffs and Class Counsel believe that the proposal contained in this supplemental submission accomplishes the Court's goals of (i) linking the distribution methodology to actual damages and providing a premium for the Group A "Heartland Drugs," consistent with the Court's prior approval of the AstraZeneca Class 1 and BMS settlements, and (ii) providing enhanced recovery for the Group B drugs. The proposed reallocation and redistribution is supported by Class Counsel and the Class Representatives, who respectfully request that the Court approve it.[2]

II. THE TRACK TWO DRUGS

A. Overview Of The Drugs

There are 145 drugs identified in Exhibit B to the Settlement Agreement. There are 7 Group A drugs, which are all single-source, brand name drugs. There are 138 Group B drugs, almost 80% of which are multi-source drugs. The majority of the Group B drugs are chemotherapy drugs or drugs often used in conjunction with out-patient chemotherapy treatment.

Attached to the Declaration of Raymond S. Hartman in Support of Track 2 Settlement Allocation (the "Hartman Declaration") filed herewith is Table 3 listing the following information for each Group B drug: drug name, including chemical equivalents; route of administration; a description of the drug's use; J-Codes; an indicator as to whether the drug is

[2] Unfortunately, mediation efforts with Don Haviland have not yet resulted in the resolution of the Haviland objections.

single-source brand, multi-brand, or multisource; whether the drug is self-administered or commonly administered in an inpatient hospital setting; the number of transactions in the claims database for the drug; and the total amount of co-pays made for the drug and the average amount each Class member paid (as per the claims database). *See also* Hartman Decl., ¶¶ 34, 39 (describing Table 3).

Dr. Hartman has also created another table that provides more detailed information. Table 4 to his declaration provides the following information by J-Code: drug name; drug group (A or B); the total out-of-pocket cost to all Class 1 claimants (the "Member Payment" column); the total number of Class 1 reimbursement records in the claims data (the "Number of Transactions" column) and what percentage this number represents (the "Percent of Transactions" column); the average amount each Class member paid for that J-Code; and an indicator of whether the average payment per Class 1 member was less than $5 and less than $10. *See also* Hartman Decl., ¶¶ 39-40 (describing Table 4).

Although the Court has not held a trial with respect to the Track Two drugs (unlike in Track One), the detailed Hartman review appearing in Tables 3 and 4, animated with substantial discussion throughout the Hartman Declaration (using methodology similar to that he employed with respect to Track One), the Berman Declaration and in this brief, should provide the Court with a robust data set with which to evaluate the Track Two drugs.

B. Summary Of Discovery

None of the drugs at issue in the Track Two settlement were added at the time that this proposed Settlement was reached as has been asserted. To the contrary, ***all*** of the drugs were subject to litigation for at least two years before this proposed Settlement was reached in March 2008, and most of the drugs have been at issue for an even longer time period. For example, ***all*** of the 145 drugs in Exhibit B are identified in the Fourth Amended Master Consolidated

Complaint Amended to Comply with the Court's Class Certification Order (the "Fourth Amended Complaint") filed on ***March 10, 2006*** and, therefore, were not added at the time of settlement in 2009 (Dkt. No. 2244).[3]

With their brief, Defendants are submitting an Exhibit B that, among other things, identifies each complaint in which the specific Track Two drug was included. As demonstrated, most of the Group B drugs were subject to litigation long before the Fourth Amended Complaint was filed. Defendants' Exhibit B also demonstrates that every Track Two Drug at issue here was subject to some sort of discovery. Rather than reproduce all of that information here and unduly burden the Court, Plaintiffs respectfully refer the Court to that filing.

Plaintiffs also refer the Court to the Declaration of Steve W. Berman in Support of Plaintiffs' Supplemental Submission in Support of a Rebalanced and Redistributed Track Two Settlement (the "Berman Decl."), filed herewith. The Berman Declaration describes with particularity the enormous amount of discovery conducted by Plaintiffs' counsel into the Track Two Defendants and drugs and which Class Counsel reviewed prior to recommending the Settlement. *See* Berman Decl., Section B. That discovery included reviewing millions of pages of documents, taking more than 120 depositions of current and former employees of Track Two Defendants, including senior managers and sales personnel (in addition to depositions of third-parties and experts), and working with reams of data and our own experts. The Berman Declaration, the bounty of supporting information provided by the Hartman Declaration and its attachments, and the significant information that the Track Two Defendants are submitting,

[3] All 145 drugs also appear in the Fifth Amended Master Consolidated Class Action Complaint Amended to Comply with the Court's Class Certification Order and Order Granting Partial Summary Judgment, which was filed on February 17, 2009 (Dkt. No. 5902).

provide the Court with sufficient detail to confidently conclude that Class Counsel had more than ample information with which to assess and recommend this proposed Settlement.[4]

C. The So-Called "Stricken" Drugs

On March 14, 2006, the Track Two Defendants moved to strike certain drugs purportedly identified for the first time in the Fourth Amended Complaint. *See* Dkt. No. 2249. The drugs targeted by Defendants were: Adenosine; Bupivacaine; Cimetidine hydrochloride; Cisplatin (Sicor's version); Depo provera/Medroxyprogesterone acetate; Dexamethasone acetate (Abbott's, Bayer's and Sicor's version); Dexamethasone sodium (Sicor's version); Ringers lactated with dextrose; Diltiazem hydrochloride; Dopamine hydrochloride; Eligard; Enalaprilat; Epinephrine; Famotidine; Glycopyrrolate; Hydromorphine; Humate-P; Ketrolac; Kogenate/Labetalol; Levofloxacin; Lidocaine hydrochloride; Magnesium sulfate; Midazolam hydrochloride; Morphine sulfate; Neostigmine methyslsulfate (Sicor's version); Pancuronium bromide (Sicor's version); Phenylephrine; Potassium acetate/Potassium chloride; Promethazine; Propofol; Sodium chloride (Sicor's version); Succinylcholine chloride; Trelstar/ Triptorelin pamoate; and Vincasar (Sicor's version). In opposition, Plaintiffs explained, *inter alia*, that most of the targeted drugs had in fact been previously at issue in the case, and that the following new drugs had been added: Depo provera, Eligard and Trelstar. *See* Dkt. No. 2335 at 3.

On April 10, 2006, the Court entered an electronic order striking any drugs that were new, simply stating "I strike the new drugs." The Court did not identify the "new" drugs in the order, but Plaintiffs understand that a "new" drug is one that was both (i) added for the first time in the Fourth Amended Complaint and (ii) for which no discovery was done up until that point in time (March 2006). Under this definition, the "new" drugs are limited to the following three:

[4] This fulsome body of evidence overwhelmingly demonstrates the falsity of Don Haviland's claim that 85 of the 145 Track Two drugs were never subjected to discovery or any analysis.

Depo provera, Eligard and Trelstar. Defendants would also add Adenosine and Ketorolac to this list, although Plaintiffs disagree (because discovery was conducted for them). In any event, the so-called "new" drugs – whether numbering three or five – are appropriately part of this proposed Settlement. They were subject to discovery before the Settlement was reached, Dr. Hartman has reviewed them (*see, e.g.,* Tables 3 and 4), and Class members will receive significant compensation for their inclusion.

III. ESTIMATED TRACK TWO DAMAGES AND THE REASONABLENESS OF THE PROPOSED SETTLEMENT

In assessing the likelihood of success at trial against the Track Two Defendants, Class Counsel – on a drug-by-drug basis – applied the Court's "three salient factors" relevant to a finding of unfair conduct as set forth in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 101-02 (D. Mass. 2007). Those three factors are: (i) where data was available, whether there were egregious spreads above the 30% yardstick expected in the industry, focusing on the extent and duration of the spreads; (ii) the company's history of creating the spread, including an analysis of whether the defendant actually increased the AWP and/or list price as opposed to just increasing the spread through discounts and rebates; and (iii) whether the defendant engaged in a proactive scheme to market the spread. Berman Decl., ¶ 3. Counsel also assessed, among other things, whether (i) the particular drug had a substantial volume of Medicare Part B reimbursements, (ii) Defendants' actions caused a significant amount of damages to the Classes in association with the particular drug, and (iii) the drug was single source or subject to multiple J-Code identification and median analysis issues, as have befallen the multi-source drugs and multi-brand biologics. *Id.*, ¶ 4.

The foregoing factors, and more, were evaluated not only to determine the reasonableness of the $125,000,000 settlement amount, but also to divide the Track Two drugs into two classifications for purposes of settlement fund distributions: Group A and Group B.[5] *Id.*, ¶ 4.

A. The Group A Drugs

Group A contains 7 brand-name drugs with unique J-Codes. Four of the drugs are manufactured by Amgen (Aranesp, Epogen, Neulasta and Neupogen); one by Aventis (Anzemet, in both tablet and injectable form); and two by Watson (Ferrlecit and Infed). Class Counsel believe that the evidence was strongest for these drugs, and this is why they were categorized in Group A and offered substantially more compensation in the original distribution proposal. Berman Decl., ¶ 6.

Spreads and overcharge ratios were particularly high for Anzemet, Neulasta, Ferrlecit and Infed. Hartman Decl., ¶¶ 28, 32 & Table 1.[6] Dr. Hartman also calculated substantial damages associated with the Group A drugs using his 30% threshold methodology, the same methodology accepted by the Court in the Track One Massachusetts trial. Damages for the seven Group A drugs totaled $317 million, with the highest damages associated with Aranesp, Neulasta, Anzemet, Ferrlecit and Infed. Hartman Decl., ¶ 14 & Attach. A1. In addition, discovery revealed substantial spread marketing evidence for these three Defendants. Berman Decl., ¶¶ 6, 26; Hartman Decl., ¶¶ 22, 27, 32. And all of the drugs were all single-source and not plagued by multiple J-Code identification issues. Given this evidence, with one exception, the Group A

[5] We have previously used the nomenclature "Class A" and "Class B" to refer to the drugs, and this has caused unintended confusion. Henceforth, we are adopting the "Group A" and "Group B" nomenclature.

[6] Spreads and overcharge ratios, though related, are distinct. Spreads are calculated by taking the difference between AWP and ASP and dividing by ASP, while overcharge ratios take the same difference and instead divide by AWP. For example, a spread of 400% would correspond to an overcharge ratio of 80%. Hartman Decl., ¶ 17 & n.13.

drugs are worthy of substantially greater compensation on a drug-by-drug basis than the Group B drugs.[7] The one exception is, of course, Epogen, as discussed further in Section IV below.

B. The Group B Drugs

Class Counsel assigned the remaining 138 drugs to the Group B pool and suggested a lower level of compensation for them because (i) most of the drugs, as multi-source, are subject to J-Code identification challenges and the median price analysis; (ii) many of the drugs are primarily administered in the inpatient hospital setting, making the level of Medicare Part B reimbursement low; (iii) many of the Group B drugs are inexpensive, resulting in a low level of Class damage (even where spreads are high); (iv) spreads on the small group of single-source branded drugs in the Group B pool tend to be small; and (v) there was a dearth of spread marketing evidence for these defendants. Berman Decl., ¶ 8; Hartman Decl., ¶ 33. For these reasons, and more, the Group B drugs account for a relatively lesser share of damages than do the Group A drugs, supporting a higher allocation of settlement dollars on a per drug basis to Group A. Hartman Decl., ¶ 50.

1. Multi-source drugs result in low damages.

Before the Settlement was negotiated, Dr. Hartman received and reviewed information for all of the Group B drugs. Hartman Decl., ¶ 34. Of the 138 Group B drugs, almost 80% of are multi-source. *Id.*, ¶ 35 & Table 3. Thus, these drugs are subject to J-Code identification challenges[8] and the median price analysis with which the Court is well versed.[9]

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[7] Thus, to be in Group A, a drug has to have most of the following characteristics: single-source, high spreads and/or spreads increasing over time, high damages, substantial spread marketing evidence for the defendant, and substantial Medicare Part B reimbursements. Berman Decl., ¶ 7.

[8] Illustrating the paradigm, the following four drugs distributed by Track Two Defendant Pharmacia share the same J-Codes as drugs that are part of the BMS settlement, which means that claimants administered these drugs are eligible to participate in both settlements: Adriamycin (doxorubicin hydrochloride), Toposar (etoposide), Neosar (cyclophospadmide) and Bleomycin. The BMS brand names for these drugs are, respectively: Rubex, Etophophos/Vepesid, Cytoxan, and Blenoxane.

In order to determine the but-for median AWPs, all AWP data for a given J-code, by quarter, would need to be gathered for ***all*** manufacturers of a given generic product. This is a daunting and burdensome task, and the difference between the actual and but-for median AWPs would most likely be small. Therefore, following this Court's findings of liability for generic drugs, damages for all multi-source generic drugs would be far less than damages calculated based on ASPs and AWPs. Hartman Decl., ¶ 35.

Nonetheless, Dr. Hartman calculated ASP and AWP spreads based on a 30% "threshold" for 37 drugs by Track Two Defendants. *See* Hartman Decl., Table 2.[10] The fictitious "damages" associated with these drugs totaled over $855 million. *Id.*, Attach. A2. ***However, and to reiterate, these "damages" are substantially overstated due to the median price issue for generic drugs reimbursed under Medicare Part B***. Actual damages will be far lower for the Group B drugs. *Id.*, ¶ 14. This was specifically considered by Class Counsel in assessing the reasonableness of the $125 million Settlement amount. Berman Decl., ¶ 9.

2. Many of the Group B drugs are predominantly administered in the hospital inpatient setting and, therefore, have low Medicare Part B utilization.

Class Counsel negotiated the Settlement aware that many Group B drugs are inpatient drugs used primarily in the hospital setting, and therefore are not commonly covered by Medicare Part B. These 72 drugs are indicated with an "X" in the "Inpatient" column of Dr. Hartman's Table 3. Examples include injectable antibiotics, such as acyclovir sodium injection,

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[9] The Court has limited damages for multi-source drugs as the difference between the actual median AWP and the "but for" median AWP had the Defendant in question reported a true AWP. *See AWP*, 491 F. Supp. 2d at 108. For example, the Court declined to find any damages for Warrick's albuterol sulfate, which was multi-source throughout the class period. *Id.* at 108. The Court has also recognized the difficulty that Plaintiffs have in identifying a particular manufacturer's multi-source drug given the interchangeability of the drugs and common J-Codes. *Id.* at 97.

[10] Overcharge ratios were not calculated for the remaining Group B drugs because Dr. Hartman did not have reasonably complete sales, chargeback, rebate and other discount data necessary to calculate average sales prices and/or the anticipated Medicare Part B utilization was too low to justify the effort.

Cipro injection, Cefizox and others; injectable anesthetics or analgesics, such as bupivacaine, fentanyl citrate, lidocaine hydrochloride, Novacaine and others; and drugs relating to nutritional concerns, such as the dextrose drugs, Liposyn II, magnesium sulfate, and others. Hartman Decl., ¶ 36. Not surprisingly, several of the predominantly inpatient drugs have either no or virtually no claims in the claims' database. *See* Table 3 and reference Aminosyn/Aminosyn II/Amino acid, Chromium tr meta/chromic chloride, Cimetidine hydrochloride, Cleocin T/Clindamycin phosphate, Dopamine hydrochloride, Humate-P, and Marcaine; *see also* Hartman Decl., ¶ 39.

These drugs would not account for substantial damages relating to Medicare Part B reimbursements. However, there are exceptions. Sodium chloride, Zemplar, Heparin and Calcijex have a fair amount of Medicare Part B reimbursements. Yet Heparin and sodium chloride are extremely low cost drugs, and both are multi-source drugs. Zemplar and Calcijex are more expensive, but only by a modest amount. Calcijex went generic in 2002, and therefore would be subject to the median price analysis discussed above after that point in time. Furthermore, spreads based on wholesaler data for Calcijex and Zemplar tend to be at or below 30%, thus indicating very low potential for damages for these drugs. Hartman Decl., ¶ 37.

3. "Low dollar" drugs also result in lower Group B drug damages.

At the time of the Settlement, Class Counsel recognized that many of the Group B drugs had relatively small out-of-pocket costs. Using the CMS data, Dr. Hartman has calculated the average member amount paid per transaction in the claims database. Hartman Decl., ¶ 40 & Table 4 (the "Average Member Payment per Transaction" column). There are ***68*** Group B J-codes (out of 187 Group B J-codes) with a per-transaction cost of $5 or less, and ***86*** Group B J-codes with a per-transaction cost of $10 or less.[11] Therefore, these drugs represent relatively low

[11] There are ***no*** Group A J-codes with average member payments less than or equal to $5 or less than or equal to $10. Hartman Decl., ¶ 40 & n.46.

out-of-pocket expenses and relatively low potential damages on a per-transaction basis, further justifying their inclusion in Group B. *Id.* ***And this is true even for drugs with high spreads***. Indeed, the vast majority of drugs appearing in Dr. Hartman's Table 2 have average member payments per transaction of less than $10, as revealed in Tables 3 and 4. Indeed, all but two have payments per transaction below $3. These drugs, along with their average member payments per transaction, are:

Aristocort/Aristospan, $1.13	Dexamethasone sodium, $.50
Dextrose/Dextrose sodium chloride, $2.59	Diazepam, $1.37
Fentanyl, $1.09	Fluorouracil, $1.27
Gentamicin, $2.04	Heparin, $.72
Lyphocin, $7.11	Methotrexate, $1.44
Sodium chloride, $2.02	Vancomcin, $7.11

This also means that, for these "low dollar" drugs, Class members will recover a substantial portion of their out-of-pocket payments (which are greater than damages, we must remember), even with the 14.08% estimated pro rata reduction (discussed below in Section IV).

4. Branded drugs in the Group B pool belong there.

The following 22 Group B drugs are considered ***single-source "branded"*** drugs, although some were eventually subject to generic competition as specified in parentheses: AccuNeb, Aromasin, Azmacort, Calcijex, Calcimar, Camptosar (irinotecan hydrochloride), Cefizox, Cipro (ciprofloxacin hydrochloride), Depo provera, Eligard, Ellence (epirubicin HCL), Enbrel, Idamycin (idarubicin hydrochloride), Leukine, Lovenox, Mithracin, Novantrone, Prograf, Taxotere, Thioplex (thiotepa), Trelstar (triptorelin pamoate) and Zemplar.

In addition, there are a number of brand names considered multi-brand "biologics" in the Group B pool. These drugs are produced from human material and are not subject to the

provisions of the Hatch-Waxman Act allowing for generic entry. Nonetheless, multi-brand biologics have multiple competing biologics, which are reimbursed using the same J-Code. Therefore, this makes them similar to multi-source drugs for reimbursement purposes. Hartman Decl., ¶ 48. The multi-brand biologics are Bebulin; Bioclate; Buminate; Gamimune N/Gammagard/Gammagard SD/Gammar/Gammar P.I.V; Helixate/Helixate FS; Iveegam; Koate-HP; Kogenate; Monoclate/Monclate-P; and Recombinate. *See* Hartman Decl., Table 3.

The Court has asked whether any of these branded drugs should be considered for movement to the Group A drug group. We do not believe so, because these drugs do not fit the single-source J-Code, high spread, high damage and rampant spread marketing paradigm of the Group A drug group.

Many of the "branded" Group B drugs have spreads that are below 30% for the vast majority of NDCs and quarters. There are a few exceptions with a few NDCs and quarters with spreads minimally above 30%. But, as a group, these drugs do not have high spreads. Given that all of these drugs have spreads either below 30% or only slightly above 30%, they do not account for substantial damages. Hartman Decl., ¶¶ 43-46. Therefore, they belong in Group B.

There are additional single-source brand-name drugs that are appropriately in Group B for which Dr. Hartman does not have wholesaler spreads. However, all of these drugs account for a very small number of transactions in the CMS data (see Table 3 to the Hartman Declaration), which is why they were not selected for analysis using the wholesaler data.[12] Therefore, all of these brand-name drugs would most likely account for a minimum of damages. Hartman Decl., ¶ 47.

[12] For example, the CMS transaction counts for some of these drugs are as follows: Aggrastat, 11; Cefizox, 174; Cipro, 129; Enbrel, 466; Humate-P, 9; Kineret (unknown due to unclassified J-Code J3490); Mithracin, 9; and Trelstar, 31.

Turning to the multi-brand biologics, they are also appropriately included in Group B. Because they share J-Codes with other drugs, including those marketed by non-defendant manufacturers, claims in the database for such drugs cannot be segregated by drug and defendant – akin to the multi-source challenge with which the Court is so familiar.[13] *Id.*, ¶ 48. In addition, several of the multi-brand biologic drugs have very few CMS transactions, such as Bebulin, Bioclate, Helixate, Koate-HP, Kogenate, Monoclate and Recombinate. *Id.*

As to other multi-brand-name drugs, they are subject to the median price analysis since the brand and the respective generic would both share the same J-code(s). Therefore, a claim for such a J-code could be based on a generic drug, and as such, would be subject to the median price analysis and the resulting minimal damages. Indeed, as time passes, generics are known to capture ever increasing market shares, with many generic drugs enjoying a 90% market share a year after introduction. This means that a multi-source J-code most likely reflects the administration of a generic drug. *Id.*, ¶ 35.

Even though we do not believe that any of the "branded" drugs in the Group B group should be moved into the Group A grouping, Class members who were administered these drugs will benefit from an enhanced Group B recovery as outlined in Section IV below.

5. Minimal-to-no spread marketing evidence was found for Group B drugs.

Class Counsel uncovered minimal spread marketing evidence associated with the Group B drugs. Berman Decl., ¶ 8. This is not surprising, given that 80% of the Group B drugs were multi-source and subject to median AWP reimbursement and that multi-branded drugs were subject to a similar paradigm.

[13] For example, Gamimune shares one or more J-codes with Gammagard, Iveegam and Gammar (which are subject to this Settlement) as well as Carimune, Panglobulin, Polygam, Venoglobulin and Baygam (which are not part of this litigation or this Settlement). Hartman Decl., ¶ 48.

IV. A MODIFIED REALLOCATION AND REDISTRIBUTION PLAN

To review, under the proposed distribution methodology submitted to the Court on July 5 in Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation (Dkt. No. 7647), a "Total Recognized Claim" is calculated for Class 1 consumers and for the Class 3 consumers who chose the "Full Estimation Refund" option instead of the $35 "Easy Pay" refund option.[14] The calculation is made by summing ***damages*** for Group A drugs (as calculated by applying Dr. Hartman's overcharge ratios to actual cash or co-pay outlays), multiplying the sum by two, and then adding out-of-pocket cash or co-payments for Group B drugs reduced proportionately based on all Group B drug claims filed.[15] Graphically, the formula is depicted as follows:

Out of Pocket *Damages* for Group A Drugs	**X 2**	**+**	**Out of Pocket Payments for Group B Drugs, reduced proportionately**	**=**	**Total Recognized Claim**

Class Counsel now propose to modify the foregoing distribution methodology further in order to enhance the fairness and reasonableness of the proposed Settlement.

The first modification proposed is an infusion of additional consumer money from the TPPs. Based on the Court's prior guidance in the BMS settlement process, Class Counsel contacted TPP Allocation Counsel and obtained an additional $3,125,000 for consumers. Berman Decl., Section C. This changes the Consumer/TPP allocation to 20%/80%. Class Counsel propose that these proceeds be used to enhance the Group B drug payout. Based on the

[14] Under the Full Estimation Refund Option, a Class 3 consumer must have provided an estimate of their total out-of-pocket expenditures during the Class Period for each Class drug for which they seek reimbursement and at least one form of documentary proof that they incurred a percentage co-pay or cash obligation outside of Medicare Part B.

[15] Importantly, the Group B payment is based, prior to proportionate reductions, on co-pays or cash pays, ***which are greater than actual damages***.

Court's prior guidance in the BMS settlement process, Class Counsel contacted TPPs and obtained an additional $3.2 million for consumers.

The Group B drug pool will be increased not only by the additional $3,125,000 contributed by TPPs, but also by three additional adjustments to the manner in which the consumer monies are distributed. First, the Court has asked whether substantial settlement monies should be allocated to Class 1 Epogen administrations given that Medicare generally did not reimburse Epogen using AWP. Epogen, an epotein alfa drug, is identical to Johnson & Johnson's Procrit. A license agreement entered into in 1985 between Amgen and Johnson & Johnson, licensed to Johnson and Johnson the exclusive right to promote and sell Procrit for non-dialysis use in the United States. As a result of this agreement, Epogen is promoted and marketed for dialysis use only in the United States. From Epogen's introduction, Medicare established a non-AWP, capitated reimbursement rate. Hartman Decl., ¶ 25 & n.27. However, it is possible that, notwithstanding the license agreement, some physicians administered Epogen instead of Procrit for non-dialysis use, even though both drugs are chemically equivalent. This was not likely a frequent occurrence, but it happened. *Id.*

In light of the fact that Medicare reimbursed Epogen for dialysis use at a capitated rate, but recognizing that ***some*** Medicare Epogen reimbursements have occurred at AWP, Class Counsel propose that the Class 1 member receive $5 for all Epogen administrations as consideration for providing a legal release. Given that most Medicare reimbursements at AWP were for Procrit and not Epogen, we expect that this change in the distribution methodology will generate approximately $1.9 million more cash for the Group B drugs.[16]

[16] We are proposing a flat payment of $50 for Class 3 Epogen administrations. The amount is larger for Class 3 because Epogen was reimbursed at AWP in the Class 3 context. However, a flat amount is still appropriate (as opposed to determining an actual overcharge), because (i) spreads for Epogen exceeded 30% only in 2003 and then

The second change proposed by Class Counsel applies to Group B drugs reimbursed by Medicare under the "not otherwise classified" J-Codes J3490 and J8999. These "not otherwise classified" J-Codes are used for drugs uncommonly reimbursed by Medicare or for new drugs that have not yet been designated with a separate and distinct J-code. Hartman Decl., ¶ 41 & n.47. The following 15 Group B drugs fall into this category: Alcohol injection, Bupivacaine, copper trace/cupric chloride, diltazem hydrochloride, Enalaprilat, Kineret, Labetalol, manganese chloride, Novacaine/Procaine, pancuronium bromide, potassium acetate, Propofol, sodium acetate, verapamil HCL and zinc chloride. Hartman Decl., Table 4 at 7. Unfortunately, there are at least 36 ***other*** drugs that fall into J3490 that are ***not*** subject to this Settlement, resulting in many claims in the CMS database for the three "not otherwise classified" drug codes. In other words, the claims that relate to J3490 are inflated and most likely sweep in a whole host of drugs that are not on Exhibit B to the Settlement Agreement and have nothing to do with this case. Hartman Decl., ¶¶ 41-42. This explains why the Total Recognized Loss for Alcohol injection, as reported in Exhibit D to the Declaration of Daniel Coggeshall Regarding Estimated Net Consumer Settlement Fund and Estimated Class 1 and Class 3 Consumer Payments for the Track Two Settlement (Dkt. No. 7648), was so high (Rust included most of the Track Two "not otherwise classified" in the Alcohol injection line item).

Given that the CMS data contains substantial reimbursements for "not otherwise classified" drugs that are excluded from this proposed Settlement, Class Counsel propose that claiming Class 1 members who were administered the foregoing 15 drugs present some documentary proof that they were administered a Track Two drug before receiving any

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minimally so (Hartman Decl., ¶ 28 & Figure 2.B); and (ii) because Rust does not have year-by-year administration data for Class 3, each year in which a Class 3 claimant was administered Epogen cannot be determined.

compensation in the Settlement.[17] Indeed, although not reflected in the data produced by CMS in this Settlement, requiring specific drug information for J3490 claims is standard practice for Medicare carriers and is reflected in the Medicare Part B claim submission instructions procedures. Hartman Decl., ¶ 42 & n.49.

It is difficult to predict with any certainty the amount of "not otherwise classified" drug claims that will result from this change, but it is not likely to be significant. For purposes of our modeling, Class Counsel have assumed that Total Recognized Claims for these drugs will drop from $5.1 million to less than $500,000.

Class Counsel propose a third and final change to the distribution formula. Defendant Immunex Corporation sold the marketing rights to Group B drugs Leukine and Novantrone to non-Defendants in 2002. Hartman Decl., Table 3 at 6-7. As such, reimbursements for these two drugs after 2002 should not be eligible for participation in the Settlement. Although we expect that this change will result in a modest decrease of about $650,000 in Total Recognized Loss, it is only fair to all Class members and will generate additional funds for distribution to all eligible Group B drug administrations.

As demonstrated in Exhibit B to the Supplemental Declaration of Daniel Coggeshall Regarding Estimated Net Consumer Settlement Fund and Estimated Class 1 and Class 3 Consumer Payments for the Track Two Settlement (the "Supplemental Coggeshall Decl."), the foregoing distribution changes, as well as the additional $3,125,000 from the TPPs, is estimated to increase the "estimated pro rata" recovery on the Group B drugs from 5.868% as reported in Dkt. No. 7648 to 14.087%, ***or a 240% increase***. And it is important to re-emphasize that these

[17] This can be done by submitting to the Claims Administrator one form of documentary proof that the Track Two drug was administered at least once. This proof can be in the form of the prescribing physician's notes in the Class member's medical file, a letter from the prescribing physician, or some other documentary evidence from the prescribing physician's office identifying the Track Two drug has having been administered at least once.

figures are ***not*** percent-of-damages metrics but, instead, a percentage of the Total Recognized Loss calculated as a function of the Class member's out-of-pocket co-pays, which are necessarily much greater than actual damages. Indeed, as discussed above in Section III.B.3, many of the Group B drug administrations will be credited a substantial portion of damages in this settlement.

In sum, the modified reallocation and redistribution plan accomplishes the following, including the changes that we recommended in Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation (Dkt. No. 7647):

1. Class 1 and 3 consumers receive ***double*** their actual damages incurred on eligible administrations of Group A drugs, ***even for administrations outside of the Court's "Heartland Period."***

2. Class 1 and Class 3 consumers administered Epogen receive a flat payment of $5 and $50, respectively, for all administrations of Group A drug Epogen, for which they incurred either minimal or no damage but for which they are providing a release.

3. Class 3 consumers electing the "Easy Pay" refund option receive a ***full*** $35 flat payment, instead of $2.04 under the original pro-ration.

4. Additional monies are allocated to the Group B drugs, resulting in more robust payouts under the original Total Recognized Loss formulation and, in many cases, a substantial percentage of their actual damages. Given the challenges posed in identifying generic drugs (due to interchangeable J-Codes) and reimbursement schemes based on median AWP (for Medicare) and maximum allowable costs (outside of Medicare), we do not believe that any further enhanced payouts for the Group B drugs are necessary. Further, there is very little spread marketing evidence for the Group B drugs. These factors have led Class Counsel to conclude that Group B damages are but a small proportion of overall Track Two damages, as supported by the Hartman Declaration.

Thus, under this proposal, ***all*** Class 1 and Class 3 consumers will receive more than their actual damages for their Group A drug administrations and will receive a lower yet substantial amount for Group B drug administrations and a modest flat payment for Epogen administrations. The Class 1 and Class 3 splits would be as follows:

- Class 1 will receive a total of approximately **$14,837,942.71** – $6,582,334.97 for Group A drugs, $8,058,317.74 for Group B drugs and $197,290.00 for Epogen. *See* Supplemental Coggeshall Decl., Ex. B.

- Class 3 will receive a total of approximately **$1,723,145.65** – $359,832.35 for Group A drugs, $898,968.31 for Group B drugs, $451,832.50 total in $35 Easy Pays and $12,512.50 for Epogen. *See* Supplemental Coggeshall Decl., Ex. B.

The splits by drug groupings would be as follows:

- Group A, $6,942,167.32;
- Group B, $8,957,286.05;
- Epogen flat payments, $209,802.50; and
- $451,832.50 in $35 Easy Pay flat payments.

The $8,957,286.05 for the Group B drugs is more than ***double*** the $4,030,393.02 previously allocated to the Group B drugs in Plaintiffs' July 5, 2011 redistribution proposal (*see* Dkt. No. 7648, Ex. D). Importantly, this estimated increase is ***not*** the result of diminishing compensation for other deserving claimants. Excluding Epogen, the Group A drug claimants still receive double their actual damages. The Easy Pay group is unaffected, and the "not otherwise classified" claimants need only demonstrate that they took a Track Two eligible drug to receive their compensation (as opposed to one of the many drugs not covered in this Settlement or litigation that are also included in the "not otherwise" classified J-Codes). The categories receiving lower compensation are the Immunex drugs Leukine and Novantrone after 2002 (because no Track Two Defendant marketed them after 2002) and Epogen, which – as demonstrated above – has little actionable damages associated with it.

The Court should authorize the provision of another notice to claimants who will receive less under the redistribution proposal than they would under the original distribution plan. The notice should advise of the changes and provide another period for comment. Class Counsel will submit a form of notice for the Court's approval on or before August 5. Approximately 41,267 claimants would receive an award amount less under this proposal than they would under the

original distribution formula. Coggeshall Decl., ¶ 10. In addition, approximate 14,448 Group B drug claimants administered a drug under a "not otherwise classified" J-Codes will also need to be re-noticed. *Id.*

Class Counsel have reviewed the proposed redistribution plan with the Class Representatives, and they approve.[18]

V. CONCLUSION

The Track Two proposed Settlement was crafted after arduous discovery. It reflects Class Counsel's considered judgment based on their deep experience in this AWP litigation and the Court's prior liability and damages decisions. The Settlement also builds upon AWP settlements that have come before. If finally approved, this Settlement will complete this complex, AWP multi-district litigation, which has been pending for a decade.

The proposed Settlement is worthy of final approval. The overall $125 million value is fair and reasonable in light of the estimated damages and the risks of proceeding to trial and beyond. The reallocation and redistribution plans embodied herein – while undoubtedly not perfect – are fair and calculated to deliver substantial recoveries to all Class members. Objections, though at times strident, have been very few.

[18] *See* Affidavit of Muriel Tonacchio in Support of Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation and In Support of Final Approval of the Track Two Settlement; Affidavit of Thomas Trusky in Support of Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation and In Support of Final Approval of the Track Two Settlement; Affidavit of Mariella Laday in Support of Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation and In Support of Final Approval of the Track Two Settlement. Counsel have been unable to reach Ms. Swayze in order to finalize her affidavit. Counsel spoke with Ms. Swayze on Friday, July 29, 2011 by telephone to discuss the redistribution with her and she expressed her approval. Ms. Swayze submitted affidavits in support of her appointment as Class 1 representative in the Track Two Settlement (Docket Nos. 7572-2, 7620). Counsel also note that Ms. Swayze was a Class 1 representative in the BMS settlement. In that capacity she was consulted concerning the redistribution of consumer funds in the BMS Settlement and submitted an affidavit expressing her support for the redistribution in that settlement. (Docket Nos. 7427, 7499). Counsel will continue to attempt to reach Ms. Swayze and will provide the Court with her affidavit as soon as it becomes available.

Class Counsel and the Class Representatives believe that the foregoing reallocation redistribution proposal is fair and reasonable and request that the Court approve both it and the Track Two Settlement.

DATED: August 3, 2011

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on August 3, 2011, I caused copies of ***Plaintiffs' Supplemental Submission in Support of a Rebalanced and Redistributed Track Two Settlement***, to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
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